CLAIMS

1. A medical device part, formed of a polymer material composition, the polymer material composition comprising at least one crystallizable base polymer and, in at least a portion of the part, further comprising a crystallization modifier, wherein from a first portion of the device part to a second portion of the device part, the polymer material composition, is varied in amount of crystallization modifier relative to the amount of said at least one crystallizable base polymer.

2. A medical device part as in claim 1 wherein said crystallization modifier amount is varied within the range of from 0 to about 20 percent by weight of the polymer composition.

3. The medical device part as in claim 1 wherein is said part is selected from the group consisting of tubes, cannulae, catheter shafts, balloons, stents, connectors, leads, laminate layers, and discreetly formed portions of any thereof.

4. A medical device part as in claim 1 wherein said crystallization modifier enhances crystallization of said base polymer.

5. A medical device part as in claim 1 wherein said crystallization modifier inhibits crystallization of said base polymer.

6. A medical device part as in claim 1 wherein said crystallizable base polymer is selected from the group consisting of olefin, acrylic, styrenic and vinyl polymers and copolymers; polyethers; polyamides; polycarbonates; polyesters; polyurethanes; thermoplastic polyimides; liquid crystal polymers; ABS (acrylonitrile butadiene styrene); ANS (acrylonitrile styrene); polyacetal; PEI (polyetherimide); polyetheretherketone (PEEK); and polyether sulfone (PES); block copolymers comprising at least one polyolefin, polyacrylic, polystyrenic, polyvinyl, polyether, polyamide, polyester, or polyurethane block therein, and mixtures of any of said polymers.

7. A medical device part as in claim 1 wherein the part is a dilatation balloon.

8. A dilatation balloon as claim 7 wherein the crystallization modifier is a crystallization inhibitor.

9. A dilatation balloon as in claim 8 comprising a balloon body portion and proximal and distal waist portions, wherein the crystallization modifier is present in the distal waist portion of the device.

10. A dilatation balloon as in claim 9 wherein the crystallization modifier is not present in the balloon body portion of the device.

11. A medical device part as in claim 1 wherein said part is a discreetly formed portion of a balloon catheter outer shaft.

12. A balloon catheter outer shaft portion as claim 7 wherein the crystallization modifier is a crystallization enhancer.

13. A balloon catheter outer shaft portion as in claim 12 comprising proximal and distal ends, the distal end adapted for bonding to a proximal waist portion of a dilatation balloon, wherein the portion of the shaft further comprising a crystallization modifier comprises a region immediately proximal of said distal end.

14. A balloon catheter outer shaft portion as in claim 13 wherein the crystallization enhancer is not present in at least one region of the catheter outer shaft portion.

15. A medical device part as in claim 1 wherein said part is a discreetly formed portion of a balloon catheter.

16. An extruded polymeric tubing segment formed of polymeric material composition comprising at least one crystallizable base polymer and having at least two

regions along the length thereof, in at least a first of said regions the polymeric material composition further comprising a crystallization modifier and the amount of the crystallization modifier in the polymer composition is different in a second region relative to said first region.

17. An extruded polymeric tubing segment as in claim 16 wherein the amount of crystallization modifier in the polymer composition varies within the range of 0 to about 30 percent by weight of the polymer composition from said second region to said first region.

18. An extruded polymeric tubing segment as in claim 16 having at least a third said region along the length thereof, in said third region the polymer comprising said crystallization modifier in an amount different than that of said first and second regions.

19. An extruded polymeric tubing segment as in claim 18 wherein the amount of crystallization modifier in the polymer composition varies substantially continuously along the length thereof.

20. An extruded polymeric tubing segment as in claim 16 wherein said crystallizable base polymer is selected from the group consisting of olefin, acrylic, styrenic and vinyl polymers and copolymers; polyethers; polyamides; polycarbonates; polyesters; polyurethanes; thermoplastic polyimides; liquid crystal polymers; ABS (acrylonitrile butadiene styrene); ANS (acrylonitrile styrene); polyacetal; PEI (polyetherimide); polyetheretherketone (PEEK); and polyether sulfone (PES); block copolymers comprising at least one polyolefin, polyacrylic, polystyrenic, polyvinyl, polyether, polyamide, polyester, or polyurethane block therein, and mixtures of any of said polymers.

21. A method of forming a polymeric part for a medical device comprising passing a mass of molten polymer material composition through an opening to form an emitted mass,

subsequently cooling the emitted mass, without substantially mixing the emitted mass material, whereby the cooled emitted mass comprises at least two regions of material located within the cooled mass in a fixed relationship to each other said fixed relationship corresponding substantially to the sequence of emission of the polymer material forming each said region,

wherein the method further comprises:

varying an amount of crystallization modifier in the polymer composition passing through said opening between the emission of the material forming the first region and the emission of the material forming the second region, whereby at least one of the two regions is provided with a positive amount of said crystallization modifier and the two regions are provided with differing amounts of said crystallization modifier.

22. The method of claim 21 wherein the amount of the crystallization modifier is varied within the range of 0 to about 20 percent by weight of the composition.

23. The method of claim 21 wherein the passing step comprises extruding said molten polymer composition through a die head.

24. The method of claim 21 wherein the passing step comprises injecting the polymer mass into a mold form.

25. The method of claim 21 wherein said polymer composition comprises a crystallizable base polymer selected from the group consisting of olefin, acrylic, styrenic and vinyl polymers and copolymers; polyethers; polyamides; polycarbonates; polyesters; polyurethanes; thermoplastic polyimides; liquid crystal polymers; ABS (acrylonitrile butadiene styrene); ANS (acrylonitrile styrene); polyacetal; PEI (polyetherimide); polyetheretherketone (PEEK); and polyether sulfone (PES); block copolymers comprising at least one polyolefin, polyacrylic, polystyrenic, polyvinyl, polyether, polyamide, polyester, or polyurethane block therein, and mixtures of any of said polymers.

26. A medical device part, formed of a polymer material composition, the polymer material composition comprising at least one crystallizable base polymer and, in at least a portion of the part, further comprising a crystallization modifier, wherein from a first portion of the device part to a second portion of the device part, the polymer material composition is continuously varied in amount of crystallization modifier relative to the amount of said at least one crystallizable base polymer.

27. A balloon catheter outer shaft portion as claim 26 wherein the crystallization modifier is a crystallization enhancer.

28. A dilatation balloon as claim 26 wherein the crystallization modifier is a crystallization inhibitor.

29. A medical device part, formed of a polymer material composition, the polymer material composition comprising at least one crystallizable base polymer,

in at least a first portion of the part, the polymer material composition further comprising a crystallization enhancer, and

in at least a second portion of the part the polymer material composition further comprising a crystallization inhibitor.

30. A medical device part, formed of a polymer material composition, the polymer material composition comprising at least one crystallizable base polymer which is partially crystallized over at least a portion of the part, wherein the degree of crystallization of said crystallizable base polymer, taken as a fraction thereof, varies over said portion.

31. A medical device part as in claim 30 wherein the medical device part is a catheter segment or catheter balloon segment, said segment having a length and a thickness dimension, and wherein said degree of crystallization varies continuously or step-wise along at least one said dimension.

32. A medical device part as in claim 30 wherein the medical device part is a catheter balloon comprising a body portion, the body portion located between opposed cone portions, the cone portions, respectively, located between opposed waist portions by which the balloon may be attached to a catheter and wherein the degree of crystallization in the waist portions is less than in the body portion.

33. A catheter balloon as in claim 32 wherein the degree of crystallization in the cone portions is less than in the body portion and greater than in the waist portions.

34. A medical device part as in claim 30 wherein the degree of crystallization is controlled by inclusion in the polymer material composition of at least one crystallization modifier which varies in amount over said portion of the part.

35. A medical device part as in claim 34 wherein the crystallization modifier comprises a crystallization enhancer.

36. A medical device part as in claim 35 wherein the crystallization enhancer is a nucleating agent.

37. A medical device part as in claim 36 wherein the nucleating agent is a member of the group consisting of carbon black, silica, kaolin, sodium bicarbonate, talc, sodium succinate, sodium glutarate, sodium caproate, sodium 4-methylvalerate, sodium-2-2'-methylenebis(4,6-di-tert-butylphenyl)phosphate, aluminum phenyl acetate, sodium cinnamate, alkali metal and aluminum salts of aromatic and alicyclic carboxylic acids, benzoic acid, naphthoic acid, tertiary-butyl benzoic acid, benzenesulfonamides, bis-(benzylidene) sorbitols, bis-(alkylbenzilidine) sorbitols, phosphate esters, norbornane carboxylic acid salts, and mixtures thereof.

38. A medical device part as in claim 34 wherein the crystallization modifier comprises a crystallization inhibitor.

39. A medical device part as in claim 38 wherein the crystallization inhibitor is a compound which ties up nucleating sites or terminates crystal propagation.

40. A medical device part as in claim 38 wherein the crystallization inhibitor. comprises a member of the group consisting of polymers and copolymers of piperylene, methylbutene, isobutene, vinyltoluene, indene, α-methylstyrene, or polycyclodiene; hydrogenated C_9 resins; pinene resins; rosin resins; terpene resins, lithium [(bis)trifluoromethanesulfonate imide.

41. A medical device part as in claim 30 wherein said crystallizable base polymer is selected from the group consisting of olefin, acrylic, styrenic and vinyl polymers and copolymers; polyethers; polyamides; polycarbonates; polyesters; polyurethanes; thermoplastic polyimides; liquid crystal polymers; ABS (acrylonitrile butadiene styrene); ANS (acrylonitrile styrene); polyacetal; PEI (polyetherimide); polyetheretherketone (PEEK); and polyether sulfone (PES); block copolymers comprising at least one polyolefin, polyacrylic, polystyrenic, polyvinyl, polyether, polyamide, polyester, or polyurethane block therein, and mixtures of any of said polymers.

42. A medical device part as in claim 41 wherein said crystallizable base polymer comprises a polyamide/polyether block copolymer or polyester/polyether segmented block copolymer.

43. A medical device part as in claim 41 wherein said crystallizable base polymer comprises a liquid crystal polymer.